REMARKS

In the Office Action of June 4, 2004, the specification was objected to for failing to include the patent number of U.S. Patent Application Serial No. 09/372,133. In the present Amendment, Applicants have amended the specification in order to correct for this informality.

Claims 1 and 2 were rejected under 35 USC § 102(b) as being anticipated by or in the alternative under 35 USC § 103(a) as obvious over Mackin (U.S. Patent No. 4,976,710) with reference to Schiff (U.S. Patent No. 4,467,790), Hanson, et al. (U.S. Patent No. 4,403,307), Bolduc, et al. (U.S. Patent No. RE29,207), and Saudagar (U.S. Patent No. 4,555,242).

Claims 3-5 were rejected under 35 USC § 102(b) as being anticipated by <u>Sahota</u> (U.S. Patent No. 5,160,320).

Additionally, claims 1-5 were rejected under the judicially created doctrine of Obviousness-Type Double Patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,264,631 and claims 1-6 of U.S. Patent No. 5,997,503.

Enclosed herewith is a proper Terminal Disclaimer from the Assignee of the present application and from U.S. Patent Nos. 6,264,631 and 5,997,503 that overcomes the Obviousness-Type Double Patenting rejection. The Terminal Disclaimer includes a certificate under 37 CFR § 3.73(b) and has copies of the Assignment and Recordation of Assignment documents for the present application and U.S. Patent Nos. 6,264,631 and 5,997,503 attached.

It is to be understood that the Terminal Disclaimer is submitted merely to expedite prosecution of the present application, and in no way should be taken as

acquiescence in the Office Action's position that a Terminal Disclaimer is required, or that the claims of the present application are obvious in view of the related patents alone or in combination with any other reference.

Applicants respectfully submit that claim 1 defines over Mackin. Respectfully, Mackin does not disclose or render obvious a balloon catheter that includes a balloon configured so that inflation of the balloon causes at least a portion of the balloon to be positioned proximally past the distal most point of a proximal cuff of the balloon. Support for this claim amendment may be found in at least Figures 9 and 10 of the drawings that show at least a portion of the balloon 218 positioned proximately past the distal most point of the proximal cuff 252 of the balloon 218. This structure may allow for enhancement of the positioning of the balloon in the internal body cavity due to urging by the balloon against the internal wall onto which the balloon is seated.

Mackin discloses a catheter 6 with balloon 7 that is inflated and urged against lining of the heart 26 in order to displace blood therefrom so that the area in question can be viewed or worked upon (see Mackin at col. 4, II. 32-44). As shown in the drawings of Mackin, for example Figures 4 and 12, the balloon 7 expands distally from the tip of catheter when inflated and unbiased. No portion of the balloon 7 is positioned proximately past the distal most point of the proximal cuff of the balloon 7 when the balloon 7 is inflated and unbiased. Additionally, it would not have been obvious for one of ordinary skill in the art to modify the structure of Mackin so that at least a portion of the balloon 7 is positioned proximally past the distal most point of the proximal cuff when the balloon is inflated. If such a structure were in fact present, the volume of the balloon 7 at this portion would cause blood to be displaced therefrom hence urging

blood towards the working well area 8 of the balloon 7. As stated in Mackin, the balloon 7 is provided in order to displace blood from the working well area 8 in order to properly observe and operate upon the portion of the heart 26 in well area 8 (see Mackin at col. 4, II. 35-44). Reconfiguring balloon 7 so that inflation of the balloon 7 causes at least a portion of the balloon 7 to be positioned proximately past the distal most point of the proximal cuff when the balloon 7 would go completely against the teachings of Mackin because doing so would in fact urge blood or other fluids back towards the working well area 8. As such, it would not have been obvious for one of ordinary skill in the art to modify Mackin in such a manner because doing so would frustrate the intended purpose of the invention.

Therefore, Applicants respectfully submit that claim 1 defines over <u>Mackin</u> with reference to <u>Schiff</u>, <u>Hanson</u>, <u>Bolduc</u>, and <u>Saudagar</u> and is in condition for allowance. Further, claim 2 that depends from claim 1 is also in condition for allowance. The rejection to claim 2 is made moot due to the allowance of claim 1.

Applicants respectfully submit that claim 3 defines over <u>Sahota</u>. Respectfully, <u>Sahota</u> does not disclose a balloon catheter in which the balloon is configured so that a proximal lobe is formed when the balloon is inflated that extends in a proximal direction at least partially past the distal most point of a proximal cuff of the balloon. Support for this claim amendment may be found in at least Figures 6 and 7 of the drawings that show a proximal lobe 176 that is formed when balloon 118 is inflated and that extends in a proximal direction at least partially past the distal most point of the proximal cuff 152 of the balloon 118.

Sahota discloses dilation catheters that are used to relive a stenotic region or to widen a constricted blood flow or tubular passage such as the coronary artery (see Sahota at col. 1, II. 10-15). The catheter shaft 14 includes a multi-lobed balloon 32 that has thin portions 36 that extend radially when inflated to dilate stenotic areas (see Figure 7 of Sahota; and Sahota at col. 6, II. 26-42). The thin portions 36 extend radially when inflated and do not form a proximal lobe that extends in a proximal direction at least partially past the distal most point of a proximal cuff of the balloon. As can be seen in Figure 7, the proximal most thin portion 36 does not extend in a proximal direction at least partially past the distal most point of the proximal cuff (a point approximately pointed to by arrow 32 in Figure 7) of the multi-lobed balloon 32. The entire multi-lobed balloon 32 is positioned distally of the distal most point of the proximal cuff of the multi-lobed balloon 32 in every single embodiment shown in the Figures of Sahota.

Further, it would not have been obvious for one of ordinary skill in the art to modify <u>Sahota</u> in order to attain the structure of claim 3. The entire point of <u>Sahota</u> is to provide a balloon that is positioned within a blood vessel in order to expand radially and hence widen the blood vessel. Extension of the balloon past the distal most point of a proximal cuff would result in a less effective design because pressure from the multilobed balloon 32 would be directed in a proximal direction as opposed to a radial direction. As stated, the entire point <u>Sahota</u> is to provide for a balloon that expands radially in order to widen the blood vessel in which it is located.

As such, Applicants respectfully submit that claim 3 defines over <u>Sahota</u> and is in condition for allowance. Further, all claims that depend from claim 3 (claims 4 and 5)

are also in condition for allowance. The rejections to claims 4 and 5 are made moot due to the allowance of claim 3.

Applicants respectfully submit that all claims are allowable and that the application is in condition for allowance. Favorable action thereon is respectfully requested. The Examiner is encouraged to contact the undersigned in order to resolve any remaining issues or should the Examiner have any questions.

Respectfully submitted,

DORITY & MANNING, P.A.

By:

Neal P. Pierotti

Reg. No: 45,716

P.O. Box 1449

Greenville, SC 29602-1449

(864) 271-1592

Fax (864) 233-7342